

## REMARKS

Claims 1-21 are pending in the above-identified patent application. Reconsideration is respectfully requested. In an effort to advance the prosecution of this application, all claims are amended and Applicant's specification is amended as well to excise reference to Figures 4 and 5. Mention of Figures 4 and 5 was clearly an inadvertency in view of the fact that the above-identified application was submitted with only two Figures. Deletion of mention of Figures 4 and 5 obviates the objection to the specification based thereon.

The rejection of Claims 1-21 under the first paragraph of 35 U.S.C. §112 is in part obviated by the foregoing amendments and is otherwise respectfully traversed. While Applicant disagrees that the term "CCK" is unclear or that one of ordinary skill in the relevant art reading Claim 1 would question what was meant, Claims 1 and 14 are amended to recite "Cholecystokinin" preceding "CCK". Applicants also respectfully disagree with the statement in the Office Action under reply that it is unclear whether the protein component a) of Claim 1 includes the proteinase inhibitor of component c). The two components are separately defined both in the specification and the Claims. Specifically, component c) is defined as an amount of plant extract sufficient to provide a specific range of the proteinase inhibitor. One of ordinary skill in the art would have no problem in reaching the conclusion that component c) is separate and distinct from a).

The rejection of Claims 4 and 6 on the grounds that whey, soy and essential amino acids are not per se proteins is in part obviated by the foregoing amendments and is otherwise respectfully traversed. In regard to whey and soy, Claim 4 is amended to recite that the component is whey protein and soy protein, respectfully. While this is abundantly clear from Applicant's specification, the amendment is made in the interest of being as precise as possible. Applicant takes issue with the assertion in the Office Action under reply that a mixture of essential amino acids is not a protein per se as being the criteria for whether the term is indefinite in the context of Applicant's invention. Applicant has set out in the specification at lines 19 and 20 of page 6 that the protein component of the subject compositions may be a mixture of

essential amino acids. That is the criteria upon which the definiteness of the term is to be judged. Since the term has been qualified by Applicant as being suitable as the protein component and as the definiteness of the term itself is not questioned in the Office Action, withdrawal of the rejection is in order and is respectfully requested.

The rejection of Claims 6 and 18 is in part obviated by the foregoing amendments and is otherwise traversed. The rejection as it pertains to missing a period at the end of the claims has been corrected. The rejection as it pertains to calcium citrate maleate is respectfully traversed. Applicant is enclosing a copy of an abstract of a paper reported in the New England Journal of Medicine, randomly selected from an on-line search, which pertains to a study conducted in 1990 by the U.S. Dept. of Agriculture demonstrating that the term was in common usage well before the filing of the above-identified patent application. A completed Form PTO-1449 for this abstract is enclosed as well.

The rejection of Claims 10 and 11 in regard to the apparent inclusion of the terms "water soluble", "natural or artificial", "extracts of" and "dyes of" within the Markush groupings is obviated by the foregoing amendments to restructure the Claims. The helpful suggestions by the Examiner in the Office Action under reply in this and several other instances are noted with appreciation.

The rejection of Claims 12 and 13 in regard to the phrase "said calorie content" is obviated by the foregoing amendments to Claim 12 to replace "wherein" with the language "further characterized in that" thereby more precisely defining the claimed limitation, and to Claim 13 to change the dependency to Claim 1 and insert the same language.

The rejection of Claims 14-21 on the grounds that they lack a recitation of essential steps is in part obviated by the foregoing amendments and is otherwise respectfully traversed. Claim 14 is amended to recite that the individual receives from about 5 to about 30 grams of a composition according to the subject invention. It is not the amount of drink containing the composition that is determinative, that is a matter of choice to the individual, e.g. some may

chose to use as little liquid as possible to effect solution or suspension while others prefer to prepare a dilute solution. That is a matter of preference over which Applicant has no control.

The amount of the composition of the present invention to be consumed before a meal may vary as well depending on the individual, since there is recognized variance among individuals. The rejection as it pertains to failure to recite an outcome is respectfully traversed. Applicant does not understand what is meant by "outcome". The claim clearly recites the object of the method as extending post meal satiety and decreasing post meal hunger. That is the "outcome". There are literally thousands of process claims in patents directed to methods of achieving a multitude of medical and pharmaceutical objects that recite no more than, "a method of treating, for example hypertension, in an individual comprising administering a specified pharmaceutical agent". Such claims do not state an "outcome". It is respectfully submitted that Claim 14 is not indefinite in failing to state an "outcome" as Applicant understands the requirement simply because there is no basis established in the record upon which one of ordinary skill in the relevant art would doubt that administration of the subject compositions to a human would have the stated effect to some degree, depending on the recognized variance among individuals alluded to above. Withdrawal of the rejection is in order and is respectfully requested.

The rejection of Claims 15 and 18 as being directed to methods, yet depending from a product claim, is obviated by the foregoing amendments to change their dependency to method Claim 14.

The rejection of Claims 1-21 under the first paragraph of 35 U.S.C. §112 as failing to provide an enabling disclosure commensurate in scope with the Claims under consideration is respectfully traversed. The Office action under reply delineates six criteria in support of the proposition that Applicant has not provided an enabling disclosure. Applicant respectfully disagrees with the conclusions drawn by the Examiner. The first criteria is the breadth of the claims. The claims under consideration are limited to compositions containing ingredients that stimulate CCK. Those of ordinary skill in the art to which the subject invention pertains are well

aware that certain proteins stimulate the release of CCK. If the experiment required to determine whether a given protein will stimulate the release of CCK has not already been carried out and reported in the literature, the ability to make the determination is clearly within the skill of the art. Hence, Applicant disagrees that the disclosure is not enabling since the claims are limited to only proteins that stimulate CCK release and representative examples have been given.

The second criteria given in the Office Action under reply is that there is an insufficient number of working examples in the specification. Again, Applicant disagrees. Applicant has given examples of representative substances for each of the components of the subject compositions and methods, and the claims are limited to only those members of the appropriate class of substances that are efficacious in stimulating CCK release. Because the claims are limited to only the members of each class of component that are effective in stimulating the release of CCK, the fact that there may be members of each of component that are not efficacious in stimulating the release of CCK is respectfully submitted to be immaterial since such substances fall outside of the scope of the claims.

The third factor discussed in the Office Action under reply is the state of the prior art and the level of skill of those in the art. It is noted that there is no actual statement in the Office Action of the level of skill of those skilled in the art, hence Applicant takes issue with the apparent suggestion that the level is not high. It is stated in the Office Action under reply that the level of skill and knowledge are insufficient to supplement the omitted description. It is Applicant's contention that the level of skill of those working in the field of dietary and nutritive research is high with many researchers possessing at least one advanced degree. The discussion in the Office Action does not focus on Applicant's Background of the Invention which documents that those skilled in the art have been aware of the effect of CCK on food intake since 1981. Given the increased level of interest in diet control and the percentage of Americans who are overweight, it can hardly be concluded that the skilled researchers in the art have little awareness of proteins and proteinase inhibitors that stimulate CCK release or how to ascertain whether a given protein or protein inhibitor would stimulate CCK release, thereby falling within the scope of Applicant's invention.

The fourth factor is predictability and here the Examiner has misplaced the emphasis. The issue is not the predictability of whether a given protein will stimulate the release of CCK because those that do not are not within the scope of the Claims. The Examiner has not challenged the predictability of whether protein and proteinase inhibitors that do stimulate the release of CCK will be effective in Applicant's compositions and methods. Regardless of the predictability of whether a given protein will stimulate the release of CCK, the means to ascertain that property are within the level of skill of the art and are not part of the claimed invention.

The fifth factor is the amount of direction or guidance and the quantity of experimentation necessary to practice the invention. This argument does not challenge the data in Applicant's specification that a representative composition is shown to be effective in extending post meal satiety, or that Applicant has failed to teach representative members of each component of the claimed composition, but rather states only that more such examples must be provided. No basis has been established of record upon which one of ordinary skill in the art would have reason to doubt that other compositions prepared according to the details given in Applicant's specification utilizing components possessing the ability to stimulate the release of CCK and a proteinase inhibitor that blocks trypsin as well as chymotrysin would be effective in the claimed method. In the absence of such basis, and given the limitations in the claims combined with the level of skill in the art, it is respectfully submitted that Applicant's disclosure provides the requisite guidance and direction concerning the practice of the subject invention required by the first paragraph of 35 U.S.C. §112.

The last factor discussed is the nature of the invention, which is actually a summary of the previous factors. Applicant respectfully takes issue with the statement that the working example does not demonstrate the claimed compositions and methods. It would appear that "not" was not intended. Applicant also takes issue with the statement that the effect of the compositions, i.e. to stimulate post meal satiety through stimulation of the release of CCK, is unpredictable since the compositions of the claims are limited to components that stimulate the



release of CCK and a proteinase inhibitor, which is known to inactivate trypsin and chymotrypsin, thereby preventing the inactivation of CCK releasing factor thus sustaining the levels of CCK released in the stomach and small intestine. The claimed compositions and method are limited to components that are effective in the release of CCK. While it is conceded that there may be natural variance among members of a class of components that are effective in stimulating the release of CCK in terms of the magnitude of their activity and some experimentation may be required to achieve optimum results with a given composition, such experimentation is respectfully submitted to be routine and not an excess burden upon those skilled in the art. Withdrawal of the rejection is clearly in order and is respectfully requested.

The rejections of Claims 1, 2 and 4-13 over Claims 1, 6, 7, 9-12, 17, 20 and 23-26 of U.S. Patent No. 6,436,899 in view of Phillips *et al.*; Claims 1, 4-11, 14, 15, 17 and 19-21 over Claims 1, 10, 12, 13, 18, 26, 27, 29, 30 and 37 of U.S. Patent No. 6,429,190 in view of Phillips *et al.*; and Claims 1, 2, 4-10, 12 and 13 over Claims 53, 60, 61, 63, 71-72,, 82, 85, 87, 92, 93, 95 and 97 of copending application Serial No. 10/211,676 in view of Phillips *et al.* all under the judicially created doctrine of obvious-type double patenting are respectfully controverted. In the third rejection, copending application Serial No. 09/817,943 is mentioned citing the same claims as were cited with regard to copending application Serial No. 10/211,676. Since Serial No. 09/817,943 is not otherwise mentioned in the rejection, it is assumed that it was not intended to be relied upon in making the rejection. If, in fact, the rejection was intended to rely on Serial No. 09/817,943, another non-final Office Action should be issued specifically indicating which claims thereof are being relied upon. However, for the Examiner's information, Serial No. 09/817,943 is abandoned. While Applicant has not as yet received a Notice of Abandonment, intent to abandon has been confirmed with the Examiner. Further, the Issue Fee has been paid in Serial No. 10/211,676, but Applicant has not as yet received notice of the patent number.

These rejections are discussed together because the reasons why they cannot be maintained apply to all. First, the two patents and pending application cited in the rejection are all antedated by the subject application. Each of the patents and the pending application have priority in application Serial No. 09/510,809, filed February 23, 2000, which issued as U.S.

Patent No. 6,207,638. The subject application claims priority from provisional application Serial No. 60/145,892 filed July 27, 1999. Therefore, neither the patents nor the publication of the copending application are prior art to the Claims under examination.

Even were it assumed for the sake of argument that the patents and copending application were available as prior art against the Claims under consideration, an obvious-type double patent rejection could still not be maintained. The inventions claimed in the patents and copending application constitute a different invention from that claimed herein. The subject compositions and method require a proteinase inhibitor as an essential component. The patents and copending application neither claim nor disclose the inclusion of a proteinase inhibitor, much less as an essential component. Hence, one of ordinary skill in the art would not consider Applicant's present compositions as an obvious variation of those disclosed and claimed in the patents and copending application. Therefore, it is respectfully submitted that an obviousness-type double patenting rejection could not be sustained over the patents and copending application.

The Examiner, in an apparent attempt to provide the missing teaching in the patents and copending application, has cited them in view of Phillips *et al.* It is respectfully submitted that the citation of a secondary, unrelated patent as in a combination rejection as is typically done in a rejection under 35 U.S.C. §103 is not permissible in an obviousness double patenting rejection. If Phillips *et al.* is intended to in some way show the knowledge of one of ordinary skill in the art regarding what might be an obvious variation of the invention claimed in the patents and copending application, that is certainly not evident from the statement of the rejection and, in any event is still not permissible in establishing an obviousness-type double patent rejection, particularly when it is considered that it is repeatedly stated in the rejections that Applicant's compositions are obvious in view of certain claims of one of the patents or copending application "in view of" or "taken with" Phillips *et al.*

Finally, and further assuming for the sake of argument, in the event that the patents and copending application were available as prior art against the Claims under consideration, the Claims under consideration would not be rendered obvious by the combination of any of them

with Phillips *et al.* The citation is related solely to the phenomenon of delayed gastric emptying. To Applicant's knowledge, there is no research study that has shown any casual connection between delayed gastric emptying and satiety. Phillips *et al.* acknowledge this in the penultimate paragraph of their background of the invention wherein it is stated that the connection between CCK secretion and gastric emptying has not yet been fully evaluated. The methods of treatment and diagnosis taught by Phillips *et al.* are intended for diabetes. Phillips *et al.* do disclose the administration of CCK, but as an alternative to Proteinase inhibitor II and via parenteral administration. There is no teaching in the citation that would suggest combining the two for any purpose. There is no teaching in the citation that would suggest any composition for a purpose other than the diagnosis and treatment of diabetes. Applicant's compositions, in distinct contrast, are intended for oral administration to healthy, non-diabetic individuals to enhance post-meal satiety achieved by combining a proteinase inhibitor with compositions similar to those disclosed in the patents. Withdrawal of the obviousness double patenting rejections is clearly in order for the reasons detailed above and is respectfully requested.

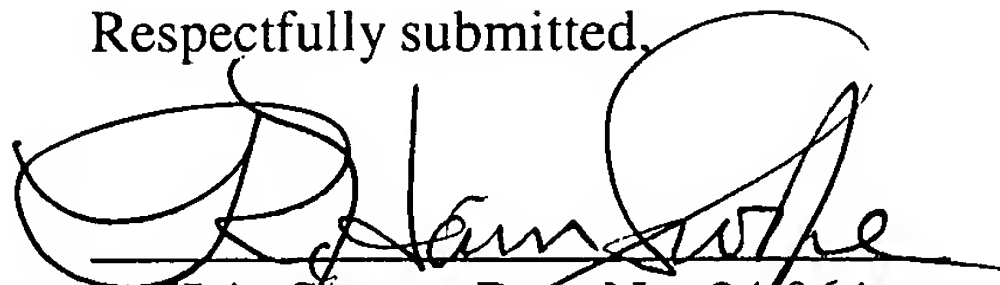
Accordingly, as Claims 1-21 meet the requirements of 35 U.S.C. §112 and are clearly patentable over Phillips *et al.*, it is respectfully submitted that this application is in condition for allowance. An early Notice of Allowance is respectfully solicited.

A Petition for a One Month Extension of Time is submitted herewith, thereby providing for the timely filing of this Amendment. Enclosed please find a check for the one month extension of \$55.00. If there are any additional fees due in respect to this reply, please charge them to Deposit Account No. 03-3839.

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